



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

KIRK COLE
INTERIM COMMISSIONER

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TTY: 1-800-735-2989
www.dshs.state.tx.us

April 17, 2015

Dear Texas Immunization Provider,

This is to inform you of a voluntary product recall of:

2014 – 2015 FLULAVAL[®] QUADRIVALENT Thimerosal-Free Pre-Filled Syringes (PFS)

All remaining doses of 2014 – 2015 FLULAVAL[®] QUADRIVALENT Pre-Filled Syringes are being recalled due to the potential for reduced efficacy of the included B strains. It is important to note that the recalled vaccine was not distributed through the Texas Vaccines for Children (TVFC) Program. The vaccine recall is not a result of any identified safety concerns.

Please read the attached letter from GlaxoSmithKline (GSK) for additional information and affected lot numbers. This recall does not affect FLULAVAL[®] QUADRIVALENT Multi Dose Vials (MDV), FLULAVAL[®] Trivalent MDV (which was distributed by the TVFC Program), or any other GSK vaccines.

For shipping assistance or questions about the recall process, please contact Stericycle at 1-877-523-9114.

Sincerely,

A handwritten signature in cursive script that reads "Kelly Patson".

Kelly Patson
Immunization Branch Manager

Enclosure: GlaxoSmithKline (GSK) Urgent Vaccine Recall Notice

URGENT: VACCINE RECALL

April 14, 2015

Re: 2014-2015 Season FLULAVAL® QUADRIVALENT
Package Size: 10 Prefilled Syringes (PFS) each containing one 0.5 mL dose
Carton NDC 19515-894-52
Syringe NDC 19515-894-41

Dear Customer:

GSK is voluntarily recalling all remaining lots of 2014-2015 FLULAVAL® QUADRIVALENT Thimerosal-Free Pre-Filled Syringes (PFS)*. As part of stability testing, GSK observed loss of potency below the minimum specification prior to product expiry for the B strains included in the vaccine. The lots are being recalled due to the potential for reduced efficacy offered by the vaccine and not as a result of any identified safety concern.

The recalled commercial lots are listed below:

Product Description	Carton NDC	Syringe NDC	Lot Number	Exp Date
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	42N4L	30-Apr-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	5AZ7H	30-Apr-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	ZS95Z	30-Apr-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	A2PK7	30-Apr-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	T3J4S	30-Apr-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	XP4J2	30-Apr-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	379MY	31-May-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	AR57J	31-May-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	2B472	30-Jun-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	9A3ZM	30-Jun-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	DR4GF	30-Jun-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	YF5DT	30-Jun-15
FLULAVAL® QUADRIVALENT TF PFS 10s	19515-894-52	19515-894-41	F45C5	30-Jun-15

*This recall does not affect FLULAVAL QUADRIVALENT Multi Dose Vials (MDV), FLULAVAL [trivalent] MDV or any other GSK vaccines.

No out of specification stability results were identified for product administered through end of 2014, the time period when the majority of influenza vaccinations occur in the US. Based on the stability results (less than 5% below minimum specification) GSK cannot rule out potential suboptimal protection for product administered from early January 2015 and beyond.

Stop distributing and immediately quarantine all listed FLULAVAL® QUADRIVALENT TF PFS 10s lots. Please carry out a physical count and record this data on the business reply card and the packing slip which are included with this letter. Please examine your inventory immediately and return all units of the listed FLULAVAL® QUADRIVALENT TF PFS 10s lots along with the Packing Slip using the enclosed UPS Return Label to:

GlaxoSmithKline, c/o Stericycle
2670 Executive Drive, Suite A,
Indianapolis, IN 46241.

It is very important that you complete the requested information on the enclosed postage paid Business Reply Card and return it to us within five (5) business days, even if you do not have the listed FLULAVAL® QUADRIVALENT TF PFS 10s lots in stock.

If you have further distributed this product, you should notify your customers so that all doses can be appropriately returned.

For shipping assistance or questions about the recall process, please contact Stericycle at 1-877-523-9114. Reimbursement will be issued at the price in effect at the time of return. In addition, reimbursement will also include a service and handling payment. Stericycle is actively notifying customer accounts. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. Thank you in advance for your cooperation.

Enclosures: Postage Paid Business Reply Card
 Packing Slip and Prepaid UPS Return Service Shipping Label